Appln No.: 09/996,128
Amendment Dated: August 7, 2005
Reply to Office Action of May 6, 2005

REMARKS/ARGUMENTS

This is in response to the Office Action mailed May 6, 2005 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Claims 28 and 29 have been added and Applicants enclose the fee for two additional dependent claims. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610. Added claims 28 and 29 are supported on Page 1, lines 10 and 11. Claims 28 and 29 are generic to the elected invention.

Claims 1, 4, 10, 11, 19, 20 and 23 stand rejected under 35 USC § 112, first paragraph. The examiner argues that the specification does not provide enablement for "the broad treatment of melanoma in a mammalian subject comprising the step of administering the broad class of xenogeneic differentiation antigens." Included in the arguments for this rejection are an assertion that the genus of differentiation antigens is a broad group, and that problems with in vivo delivery and expression of the broad group are not overcome. Applicants respectfully disagree with this rejection.

As a first matter, Applicants point out that the definition that the Examiner cites is for differentiation antigens generally. The independent claims are not this broad, however, and are limited to "xenogeneic differentiation antigen of the same type as **a differentiation antigen expressed by melanoma cells** of the subject." The specification, at page 1, lines 10-11 identifies four types of melanoma differentiation antigens, and these are expressly recited in claims 28 and 29. The Examiner has not established that differentiation antigens associated with melanoma cells are a broad class.

The Examiner also bases the enablement rejection on the teaching of Eck et al. Applicants respectfully submit, however, that the variability and uncertainty described in Eck is not really applicable to the present application. The Eck et al. chapter relates to a broad range of "therapeutic gene therapy." The Examiner summarizes this document by stating that "the state of the art regarding *in vivo* delivery of nucleic acids is highly unpredictable. This statement is too broad, however, because the claimed invention is not this broad. The claimed invention only requires gene transfer and expression to the extent necessary to produce an immune response to the expressed protein. There are no specific target cells, nor is duration of expression for any significant time required. Clearance of expressed protein is not a significant issue, and increased clearance can in fact result from the generation of the immune response. Thus, the types of problems which the Examiner notes as associated with the broad concept of therapy are not of any apparent relevance to the present invention.

The Examiner has also not stated why the two vectors, one encoding human tyrosinase and one encoding mouse tyrosinase would not be enabling for use of immunization against tyrosinase in any species, since one vector or the other (if not both) would always be xenogeneic with respect to any given individual being treated.

Applicants also note that the specification teaches a vector containing human gp75 and its use in the immunization of mice (Example 5, Pages 9-10).[1] Further, the application provides several standard options for promoters and the basic protocols for genetic immunization. (Page 5-6).

The Examiner has not explained why, given *in vivo* examples in two species with two different melanoma differentiation antigens and the presentation of a mechanistic basis for the observed results, the person skilled in the art would not accept the statement of broader applicability as set forth in the specification and claims. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971)(a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patents must be taken as in compliance with the enabling requirement of the first paragraph of § 112, unless there is a reason to doubt the objective truth of the statements contained therein, which must be relied upon for an enabling disclosure.) The generalized text relating to gene therapy, and the problems that may be encountered in some instances does not provide the specificity necessary to establish a reason to doubt the statements made in this case, given the evidence of record. Accordingly, Applicants submit that the rejection for lack of enablement should be withdrawn.

The Examiner also provisionally rejected claims 1, 2, 4, 5, 10-12 and 19-23 for obviousness type double patenting in view of Application Serial No. 10/041,410. Applicants will file a terminal disclaimer if it is appropriate when an indication of allowability is received. It is noted that Application Serial No. 10/041,410 has not yet had an action on the merits, although a restriction requirement has been mailed.

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[1] While gp75 is not the elected species, the disclosure is fully relevant with respect to enablement, particularly since the enablement rejection is only applied to the generic claims that encompass gp75.

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For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

Marina T. Larson, Ph.D
Attorney/Agent for Applicant(s)
Reg. No. 32038

(970) 468 6600

Enclosures:

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